

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

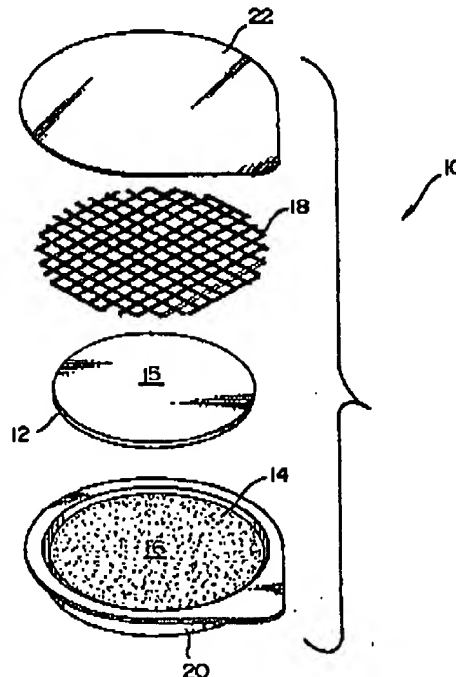
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: A61B 8/00	A1	(11) International Publication Number: WO 98/29036
		(43) International Publication Date: 9 July 1998 (09.07.98)
(21) International Application Number: PCT/US97/24262 (22) International Filing Date: 24 December 1997 (24.12.97) (30) Priority Data: 08/777,581 31 December 1996 (31.12.96) US (71) Applicant: DIAGNOSTIC ULTRASOUND CORPORATION [US/US]; P.O. Box 818, Redmond, WA 98073 (US). (72) Inventor: PRETLOW, Robert, A. ; 5406 Lake Washington Boulevard Northeast #K, Kirkland, WA 98033 (US). (74) Agent: PUNTIGAM, Clark, A. ; 2033 - 6th Avenue #1020, Seattle, WA 98121 (US).		(51) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: **COUPLING PAD FOR MEDICAL ULTRASOUND DEVICES**

(57) Abstract

A pad assembly for coupling ultrasound from a transducer probe into the human body includes a shallow receptacle (20) with a removable cover (22) on the upper portion thereof. Within the receptacle are foam section (14), a gel pad (12), and a thin net section (18). The net section (18) is bonded to the cover (22). The gel pad (12) is impregnated with a mixture of glycerin and water. The upper surface of foam section (14) is convoluted or ribbed so that there is a substantially lower surface tension between the foam section (14), and the gel pad, than between probe and the gel pad. There is also a substantially lower surface tension between net section (18) and the gel pad, than between the gel pad and the foam section.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroun	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

WO 98/29036

PCT/US97/24262

Description

COUPLING PAD FOR MEDICAL ULTRASOUND DEVICES

5

Technical Field

This invention relates generally to ultrasound medical devices, and more specifically concerns a coupling member for coupling ultrasound signals between an ultrasound transmitter/receiver probe or head and the skin of the patient.

Background of the Invention

Medical ultrasound scanning devices generate and transmit sound energy, typically in a frequency range of 2-10 megahertz, into the human body and then detect the returning echo signals from the body. Since the medium of air significantly attenuates the ultrasound frequencies used in medical applications, a coupling medium, typically a gel material, is used between the surface of the ultrasound probe and the skin of the patient, in order to displace the air therebetween. Such gels, however, which are liquid or semi-liquid, are inconvenient to use and have several other disadvantages. They are cold and unpleasant to the patient, they often result in wetting the patient's clothing, and they typically require a substantial amount of time for the ultrasound technician to clean up. It would be desirable to have a coupling medium or member which is easier to use and more convenient than such a gel.

30

Disclosure of the Invention

Accordingly, the present invention is a pad assembly which includes a member for coupling ultrasound signals from an ultrasound probe into the human body, comprising: a pad adapted for coupling of ultrasound signals between an ultrasound probe and a human body; a support member on which said pad is positioned, wherein the support member is characterized by an upper surface which is configured and arranged to have a lower surface tension between it and the pad than that between the ultrasound probe and the pad, so that when the probe is pressed against

40

WO 98/29036

PCT/US97/24262

2

the pad and then lifted, the pad remains with the probe, wherein the probe can then be positioned adjacent the desired skin area of the body, the pad being between the probe and the desired skin area; and a receptacle for the pad and the support member.

Brief Description of the Drawings

Figure 1 is an exploded view of the gel pad assembly of the present invention.

Figure 2 is a cross-sectional view of the gel pad of Figure 1 as an ultrasound probe is initially brought into contact therewith.

Figure 3 is a cross-sectional view showing an ultrasound probe with the gel pad of Figure 1 positioned on a skin portion of a patient.

Figure 4 is a schematic view of a first step in the use of the gel pad assembly of Figure 1.

Figure 5 is a schematic view showing a second step in the use of the gel pad assembly of Figure 1.

Figure 6 is a schematic view showing the third step in the use of the gel pad assembly of Figure 1.

Best Mode for Carrying Out the Invention

Figure 1 shows the gel pad assembly 10 of the present invention. The gel pad assembly includes a relatively thin (approximately 0.06 inches) gel pad 12 which in use is positioned between an ultrasound transducer probe and a selected skin area of a patient. In the embodiment shown, gel pad 12 is circular, approximately 2.5 inches in diameter, and is made from cellulose or equivalent material, typically impregnated with a mixture of glycerin and water, or other liquid suitable for ultrasound coupling, such as certain oils, including generally water-soluble glycols, such that the opposed surfaces of the pad are pliable, wet and slippery, and will displace any air between the pad and the skin surface and between the pad and the probe surface.

The term gel pad is used herein as a descriptive, inclusive term to mean a pad having the above described characteristics, displacing air as indicated, even though "gel" per se may not be used in the pad.

WO 98/29036

PCT/US97/24262

3

5 Gel pad 12 is an effective coupling medium between an ultrasound transducer probe and the body of the patient, preventing signal attenuation which would occur in the absence of such a coupling member. Gel pad 12 could comprise multiple layers, with the outer layers having the above-described characteristics which displace air from between the pad and the probe and the patient's skin, respectively.

10 As explained above, in present practice, a given amount of a conventional liquid or semi-liquid ultrasound gel is placed either on the transducer probe, the desired skin area of the patient and/or both. The probe is then positioned on the desired skin area, directly on the gel, and the ultrasound procedure is then begun. The present invention replaces the conventional use of the ultrasound gel. The ultrasound probe used with the present invention and discussed herein may have various configurations, but generally refers to the transducer/receiver member which is connected to an ultrasound generating device for transmitting ultrasound signals into a desired area of the body and to receive returning signals therefrom. It should be understood that the ultrasound probe per se is not a part of the present invention.

25 Ultrasound is currently used for a wide variety of diagnostic and monitoring purposes, including, for example, monitoring the development of a fetus within the womb and investigating the condition of various areas of the heart and/or the arterial system supplying blood to the heart. There are numerous other applications for ultrasound in the medical field.

30 Gel pad assembly 10 further includes a circular section of foam 14. In the embodiment shown, the foam section 14 is approximately 2.5 inches in diameter (approximately the same diameter as gel pad 12) and 0.135 inches thick. Upper surface 16 of foam section 14 is either open cell (with a relatively large cell size, typically 0.020 inches in diameter) or is convoluted or ribbed. The convolutions may take various configurations; the intent is to create a rather low surface tension between upper surface 16 of foam section 14 and the adjacent surface of gel pad 12. Gel pad 12 rests on the upper surface of foam section

WO 98/29036

PCT/US97/24262

4

14 in the gel pad assembly but is not otherwise secured thereto.

5 Resting against upper surface 15 of gel pad 12 is a thin plastic net section 18, which has the same diameter and configuration as gel pad 12 and foam section 14, but in the embodiment shown is considerably thinner than foam section 14, approximately 0.03 inches. Net section 18 is typically made of polypropylene or any other thin plastic material with a weave opening size approximately 0.125
10 inches in diameter. Basically, the purpose of the plastic net section 18 is to prevent gel pad 12 from adhering to a cover 22 of the assembly. Net section 18 presents a surface tension to the gel pad that is lower than that presented by the foam section 14, so the gel pad will remain on foam section 14 when cover 22 is removed. The net section 18 is adhesively bonded to cover 22.

The three elements 12, 14 and 18 discussed above are positioned in a receptacle which includes a lower cup portion 20 and cover portion 22. Cup portion 20 is shallow,
20 approximately 0.25 inches high, and has an internal diameter which is large enough to accommodate gel pad 12, foam section 14 and net section 18. Cup portion 20 in the embodiment shown is made of thin plastic, such as polyester. Cover portion 22 overlays net section 18, with net section
25 18 being bonded to the cover portion; cover portion 22 is secured around the periphery thereof to the upper edge of cup portion 20, typically by means of an adhesive.

In use of gel pad 12, cover portion 22 is first removed from cup portion 20, simultaneously removing net section 18, as shown in Figure 4. The attachment and removal of cover 22 can be accomplished in a number of ways.
30 If an adhesive is used, typically the entire cover will be pulled away by the user. Gel pad 12 is now exposed.

At this point, the ultrasound transducer probe 30
35 is brought into contact against the upper surface of the exposed gel pad 12, as shown in Figure 5 and the arrow therein. A cord provides a signal connection between transducer probe 30 and the ultrasound generating and processing apparatus. The ultrasound probe 30 will
40 typically include a curved or partially domed portion 34. Domed portion 34 is adapted to be placed on the desired skin

WO 98/29036

PCT/US97/24262

5

area of the patient. Typically, domed portion 34 is quite smooth so that it has a relatively high surface tension when it contacts the gel pad; in particular, the surface tension is much greater than that of the upper surface of foam section 14. Domed portion 34 is pressed against the upper surface of gel pad 12. The physical relationship between domed surface 34 of probe 30, gel pad 12 and foam section 14 at this point is shown most clearly in Figure 2.

In the next step, as shown in Figure 6, probe 30 is lifted away from the gel pad assembly. However, because the surface tension between gel pad 12 and domed portion 34 is significantly higher than the surface tension between the gel pad and the foam section, gel pad 12 remains fixed to domed portion 34 as the probe is moved away. Hence, gel pad 12 remains positioned firmly on the domed portion of the probe without the operator having to come into contact with the gel pad itself or any of the glycerin thereon.

In the next step, the ultrasound probe with the gel pad thereon is positioned on the desired skin area of the patient. The gel pad lies against the skin and provides an effective coupling medium between ultrasound probe 30 and the patient's body. Because the gel pad is pliable, slippery and wet, it displaces any air between the pad and the skin of the patient, including any skin irregularities caused by hair, as well as any air between the pad and the surface of the probe. The relationship is illustrated in Figure 3, showing probe 30, gel pad 12 which is positioned on the domed portion 34 of the probe, and the skin area 35 of the patient.

At this point, operation of the ultrasound device can begin, with ultrasound signals being generated and transmitted into the body of the patient through the gel pad coupling element; the returning echo signals from the body are also received through the gel pad. When the procedure is completed, the ultrasound probe along with the gel pad is removed from the patient's body. Because the surface tension between the probe and the gel pad is higher than that between the gel pad and the skin, the gel pad remains in place on the probe when the probe is removed from the skin. Any residual glycerin/water mixture from the gel pad, which is typically minimal, left on the skin of the

WO 98/29036

PCT/US97/24262

6

patient is either left there to be absorbed into the skin or quickly (and conveniently) wiped clean.

Any residual glycerin/water mixture on the probe dome 34 is also wiped away. Foam section 14 which remains in cup portion 20 and cup portion 20 itself may be discarded or may be used to remove the gel pad from the probe. By pressing the probe with the gel pad in place back on the foam section 14 and sliding the probe and the gel pad laterally against the lip of cup portion 20, the gel pad can be removed from the probe without the operator having to come into contact with the gel pad. The used gel pad 12, cup portion 20 and foam section 14 can then all be discarded.

Hence, a gel pad assembly has been disclosed which provides a convenient and effective coupling medium between the ultrasound probe and the skin without the disadvantages of conventional liquid or semi-liquid gel.

Although a preferred embodiment of the invention has been disclosed herein for illustration, it should be understood that various changes, modifications and substitutions may be incorporated in such embodiment without departing from the spirit of the invention, which is defined by the claims as follows:

WO 98/29036

PCT/US97/24262

7

Claims

1. An ultrasound coupling assembly, comprising:
a pad adapted for coupling of ultrasound signals between an ultrasound probe and a human body;
a support member on which said pad is positioned, wherein the support member is characterized by an upper surface which is configured and arranged to have a lower surface tension between it and the pad than that between the ultrasound probe and the pad, so that when the probe is pressed against the pad and then lifted, the pad remains with the probe, wherein the probe can then be positioned adjacent the desired skin area of the body, the pad being between the probe and the desired skin area; and
a receptacle for the pad and the support member.
2. An article of claim 1, wherein the pad is pliable.
3. An article of claim 1, wherein the support member is foam and the upper surface thereof is convoluted.
4. An article of claim 2, wherein the pad is impregnated with an ultrasound conducting liquid, the liquid acting to displace air between the pad and the probe, as well as between the pad and the desired skin area when the probe and the impregnated pad are operatively positioned on the desired skin area.
5. An article of claim 1, wherein the support member is a large open cell foam material.
6. An article of claim 1, including a removable cover portion which extends over and covers the pad and the support member and is secured to an upper edge of the receptacle.
7. An article of claim 6, including a thin net member positioned between the pad and the cover portion, wherein the net member is attached to the cover portion and wherein the surface tension between the net member and the pad is less than that between the pad and the support member, so that when the cover portion is removed, the pad remains on the support member.

WO 98/29036

PCT/US97/24262

8

8. An article of claim 1, wherein the surface tension between the pad and the probe is greater than the surface tension between the pad and the desired skin area of the body, so that as the probe is moved away from the body, the pad remains with the probe.

9. An article of claim 1, wherein the pad, the support member and the net member have approximately the same configuration and outline.

10. A pad for use with an ultrasound probe for coupling ultrasound signals into a human body, comprising:

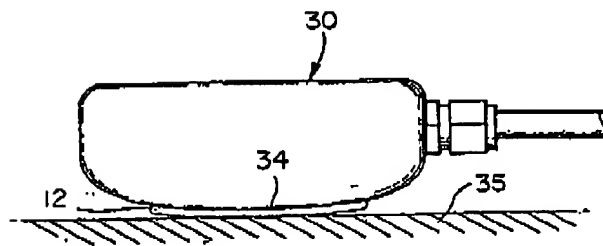
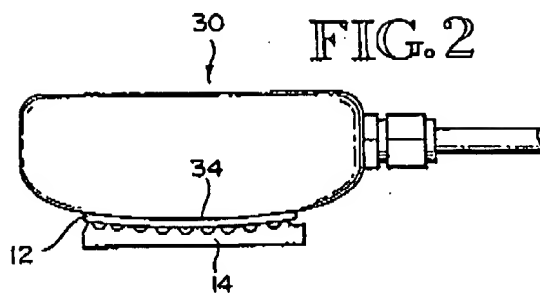
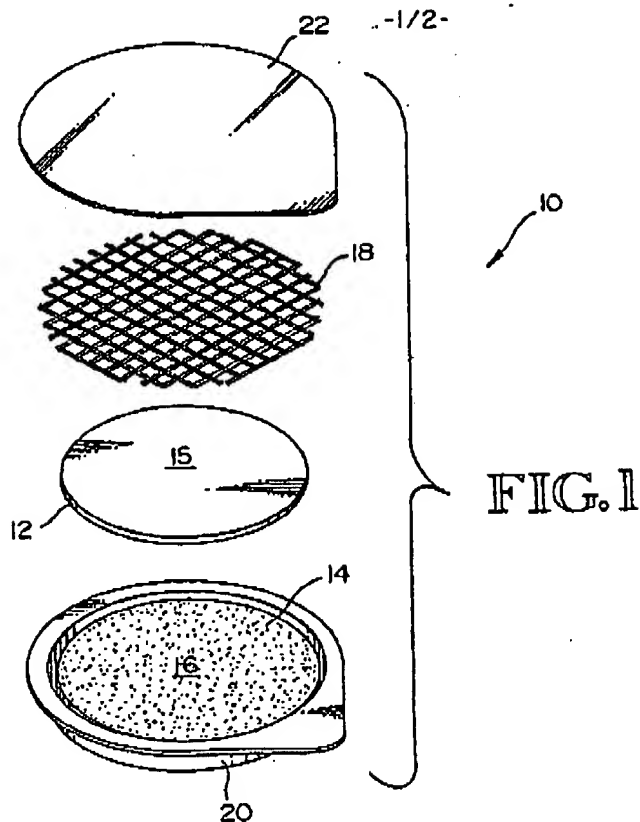
a pad member, made of a material which, when impregnated with an ultrasound conducting liquid, is capable of conducting ultrasound signals from a probe source thereof into a skin area of the human body, the impregnated pad being pliable and wet at its respective opposed surfaces so that any air between the pad and, respectively, the probe and the skin area is displaced when the pad is positioned between the probe and the skin area.

11. An article of claim 10, wherein the pad material is cellulosic material.

12. An article of claim 10, wherein the liquid is a combination of water and glycerin.

WO 98/29036

PCT/US97/24262



SUBSTITUTE SHEET (RULE 26)

WO 98/29036

PCT/US97/24262

- 2/2 -

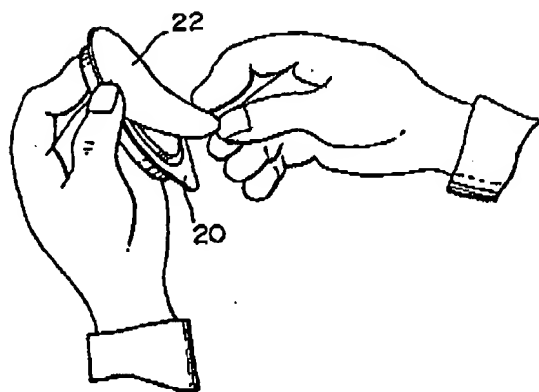


FIG. 4

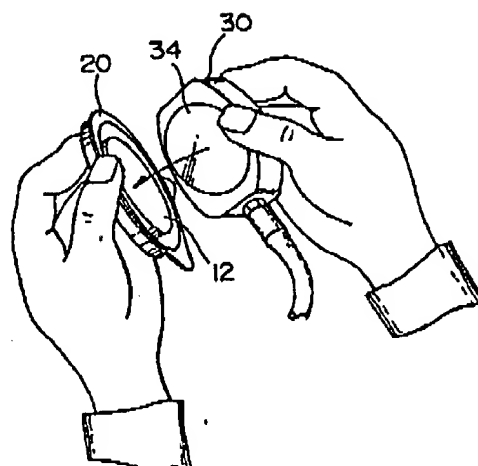


FIG. 5

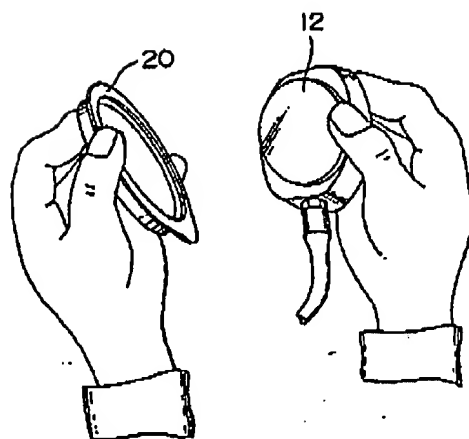


FIG. 6

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/24262

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 8/00

US CL :600/437

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/437

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,265,614 A (HAYAKAWA et al.) 30 November 1993, entire document.	10-12
Y	US 4,556,066 A (SEMROW) 03 December 1985, entire document.	1-9
Y	US 5,076,149 A (EVERTS) 07 January 1992, entire document.	1-12

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

B earlier documents published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O documents referring to an oral disclosure, use, exhibition or other means

P documents published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combinations being obvious to a person skilled in the art

A document member of the same patent family

Date of the actual completion of the international search

02 MARCH 1998

Date of mailing of the international search report

07 APR 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer

MAULIN PATEL

Telephone No. (703) 305-6933

Form PCT/ISA/210 (second sheet) (July 1992)*